K083422

510(k) Summary

FEB - 6 2009

Submitter:	Medtronic Vascular 37A Cherry Hill Drive Danvers, MA 01923
Contact Person:	Vic Zhang Regulatory Affairs Specialist Phone: (978) 739-3080 Fax: (978) 777-0390 Email: vic.zhang@medtronic.com
Date Prepared:	November 14, 2008
Trade Name:	Medtronic 6F Taiga™ Guiding Catheter
Common Name:	Guiding Catheter
Classification Name:	Percutaneous Catheter
Predicate Device:	Medtronic 6F Sherpa NX (Z4) Guiding Catheter, K042489
Device Description:	The 6F Taiga™ Guiding Catheter is a single lumen catheter with an atraumatic tip, which provides a pathway for therapeutic devices to be introduced into the coronary or peripheral vascular system.
Statement of Intended Use:	Provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used in the coronary or peripheral vascular system.
Summary of Technological Characteristics:	**Luer hub:** Allows interfacing of the catheter with other devices. **Outer jacket:** The outer jacket provides the catheter with its ability to retain its curve, and also provides additional support. **Wire braided shaft:** Provides the catheter with torque response and crush resistance. **Inner liner:** Provides sufficient lumen lubricity for therapeutic device to pass through. **Distal segments:** Allow a transition of catheter stiffness from the proximal catheter shaft to the soft distal tip. **Soft tip:** Minimizes the potential for vessel trauma when the catheter is advanced in the vasculature system.
Summary of	Medtronic 6F Taiga™ Guiding Catheter has successfully

Non-clinical Data:	passed all design verification and validation testing.
Summary of Clinical Data:	No clinical investigation has been performed for this device.
Conclusion from Data:	Medtronic Vascular has demonstrated that the 6F Taiga Guiding Catheter is substantially equivalent to the predicate devices based on its indications for use and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Medtronic Vascualr
c/o Vic Zang, Ph.D.
Regulatory Affairs Specialist
37A Cherry Hill Drive
Danvers, MA 01923

Re: K083422
Medtronic 6F Taiga™ Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II
Product Code: DQY
Dated: January 8, 2009
Received: January 9, 2009

Dear Dr. Zang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Zuckerman

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K083422

Device Name: Medtronic 6F Taiga™ Guiding Catheter

Indications for Use:

The Medtronic Guiding Catheter is designed to provide a pathway through which therapeutic devices are introduced. The guiding catheter is intended to be used in the coronary or peripheral vascular system.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan R. Mitchell
(Division Sign-Off)
Division of Cardiovascular Devices

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